UCB News

Brussels (Belgium), 24 June 2022 – 7:00 (CEST) – regulated information – inside information

UCB updates financial guidance for 2022 while maintaining 2025 financial guidance

- UCB aims to submit the response to the bimekizumab complete response letter (CRL) by the end of 2022, triggering a later potential launch date in the U.S.
- Zogenix integration: earnings dilution in 2022, earnings accretive expected from 2023 onwards
- Combination of unprecedented, multiple external headwinds and difficult macro situation lead to upward pressure on costs
- Updated financial guidance for 2022: Revenue expected in the range of € 5.3 - 5.4 billion, adjusted EBITDA[2] in the range 21 - 22 % of revenue, Core EPS[3] in the range of € 3.70 - 4.00
- Financial guidance for 2025 unchanged

UCB is updating its 2022 financial guidance factoring in the impact of the Zogenix acquisition, the complete response letter for bimekizumab in the U.S. and macro-economic conditions. UCB's foundation for growth is strong as demonstrated by recent positive clinical phase 3 study results which will lead to regulatory submissions starting next quarter. The company is confident in its ability to deliver value and growth for patients and all other stakeholders through its strong fundamental underlying performance. UCB reiterates its 2025 financial guidance.

Jean-Christophe Tellier, CEO UCB says: "We aim to submit our response to the complete response letter by the end of the year – and are fully committed to bring bimekizumab as treatment option to people living with psoriasis in the U.S. We are updating our financial guidance, reflecting the most recent events and the current macro situation. UCB's underlying performance is solid, despite the impacts from the loss of exclusivity for E KEPPRA® in Japan since January and for VIMPAT® in the U.S. since March. We are very confident in our future launches and our strategic growth path ahead, supported by dynamic management and efficiency initiatives in all areas of UCB. Our drive to create value for patients, now and into the future, remains stronger than ever."

Bimekizumab complete response letter response timing

UCB aims to submit the response to the bimekizumab complete response letter (CRL) to the U.S. Food and Drug Administration (FDA) by the end of 2022. UCB will address all observations and questions noted in the CRL and is fully confident in the quality of its manufacturing process. Upon receiving the response, the FDA will classify the response following the re-submission. A Class 1 re-submission would imply a 2-month review cycle by the FDA post the re-submission date, and a Class 2 re-submission would imply a 6-month review cycle post the re-submission date.

Updated financial guidance 2022

- **Zogenix acquisition**

Following the close of the Zogenix, Inc. acquisition in early March 2022, the full integration process is nearly complete. This acquisition is now for the first time reflected in UCB's financial guidance. Together with the team from Zogenix, UCB is bringing FINTEPLA® (fenfluramine) oral solution to patients and their families around the world living with Dravet Syndrome and Lennox-Gastaut Syndrome (LGS). FINTEPLA® is available in the U.S and Europe to treat seizures associated with Dravet Syndrome. In June, UK's National Institute for

Healthcare Excellence (NICE) issued a positive Final Appraisal Determination (FAD) recommending FINTEPLA® (fenfluramine) oral solution for the treatment of seizures associated with Dravet Syndrome as an add-on therapy to other anti-epileptic medicines for patients two years of age and older. Since late March 2022, FINTEPLA® is approved in the U.S. for the treatment of Lennox-Gastaut Syndrome (LGS), in patients two years of age and older. The application review for LGS in the EU and other regions is ongoing.

The new financial guidance for 2022 takes into account the expected net sales contribution from FINTEPLA® as well as the additional research and development, marketing and selling and other expenses, leading to a dilution of the UCB earnings, consistent with UCB's assessment at the time of the acquisition. The dilution to UCB's adjusted EBITDA guidance is expected around 2.5%-points in 2022. The acquisition is expected to be earnings accretive from 2023 onwards.

- **Bimekizumab complete response letter impact**

UCB aims to submit the response to the bimekizumab complete response letter (CRL) to the U.S. Food and Drug Administration (FDA) by the end of 2022. Adjustments to the 2022 financial guidance removed the 2022 net sales contribution in the U.S., adjusted the expenses while ensuring that the expected launch is secured and reflect the gross profit and tax implications.
Since the second half of 2021, BIMZELX® (bimekizumab) is available to people living with psoriasis in the European Union /European Economic Area, Great Britain, Japan, Canada and approved in Australia.

- **Macro environment adding up**

Multiple external headwinds combined with a difficult macro-economic situation are leading to upward pressure on costs - like significantly higher than anticipated inflation including energy costs, the war in Ukraine including drug supply and donations to Ukraine. These were reflected in the new updated financial guidance for 2022.

- **Adjusted financial guidance for 2022**

For 2022, UCB is now aiming for revenues in the range of €5.3 – 5.4 billion based on continued core product growth and taking into account impacts from the loss of exclusivity for VIMPAT® in the U.S. (March) and Europe (September) and the strong generic competition to E KEPPRA® in Japan since January.

UCB continues to invest in research and development to advance its late-stage development pipeline and prepare for upcoming launches to offer potential new solutions for patients. Underlying profitability, adjusted EBITDA, is now expected in the range of 21 - 22% of revenue, also reflecting the continued research and development and marketing & selling investment levels. Core earnings per share are therefore expected in the range of €3.70 - 4.00 per share – based on an average of 189 million shares outstanding.

The figures for the new financial guidance 2022 as mentioned above are calculated on the same basis as the actual figures for 2021; they have been extended by the consolidation of the acquisition of Zogenix, Inc.

UCB will publish its Half-Year Report 2022 on July 28, 2022.

2025 financial guidance –confirmed

Supported by solid multiple scenario planning and sustainable efficiency generating initiatives in all areas of UCB - being introduced since Q4 2021 - UCB maintains its financial guidance for 2025. Revenue in 2025 is expected to reach at least € 6 billion and the underlying profitability (adjusted EBITDA) should reach the low to mid-thirties in percent of revenue.

Based on UCB's current assessment of the Covid-19 pandemic, UCB remains confident in the fundamental underlying demand for its products in the short-term and its prospects for long-term growth. UCB will continue to closely follow the evolving COVID-19 pandemic and its consequences to the business environment diligently to assess potential near- and mid-term challenges.

[2] adj. EBITDA = adjusted Earnings Before Interest, Taxes, Depreciation and Amortization charges
[3] Core EPS = core earnings per share

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About UCB
UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With approximately 8 600 people in approximately 40 countries, the company generated revenue of € 5.8 billion in 2021. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

Forward looking statements
This press release contains forward-looking statements including, without limitation, statements containing the words "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will", "continue" and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guaranteeing of future performance and are subject to known and unknown risks, uncertainties and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to differ materially from those that may be expressed or implied by such forward-looking statements contained in this press release.
Important factors that could result in such differences include but are not limited to: global spread and impacts of wars and pandemics. Including COVID-19, changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws, and hiring and retention of its employees. There is no guarantee that new product candidates will be discovered or identified in the pipeline, or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The

length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB' efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB's products that implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB's data and systems.

Given these uncertainties, you should not place undue reliance on any of such forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labelling in any market, or at any particular time, nor can there be any guarantee that such products will be or will continue to be commercially successful in the future. These forward-looking statements are made only as of the date of this press release, and do not reflect any potential impacts from the evolving war in Ukraine and COVID-19 pandemic, unless indicated otherwise. The company continues to follow the development diligently to assess the financial significance of this to UCB.

UCB is providing this information, including forward-looking statements, only as of the date of this press release and expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report or reflect any change in its forward-looking statements with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless such statement is required pursuant to applicable laws and regulations.

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